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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|--|-------------|----------------------|---------------------|-----------------------|--|--|
| 10/659,451 | 09/09/2003 | Maria Villani | 51331-00004 | 4939 | | |
| 45200 | 7590 | 04/30/2008 | EXAMINER | | | |
| KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319 | | | | SRIVASTAVA, KAILASH C | | |
| ART UNIT | | PAPER NUMBER | | | | |
| 1657 | | | | | | |
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| 04/30/2008 | | PAPER | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/659,451 | VILLANI, MARIA | |
| | Examiner | Art Unit | |
| | Dr. Kailash C. Srivastava | 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 January 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,7,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3,7,24 and 25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Response and amendment filed 23 January 2008 to Office Action mailed 16 November 2007 is acknowledged and entered. The text of those sections of Title 35, U.S. Code (i.e., U.S.C.) not included in this action can be found in a prior office action.

Withdrawals in View of Applicant's Amendments and Arguments

2. In view of remarks and amendment filed 23 January 2008, the following objections and Rejections in the Office Action mailed 16 November 2007 are hereby withdrawn:

- To specification for perfecting the citation of priority data and correcting grammar in the body of the specification;
- To Claims 1, 3, 7 and 24-25 for not citing the name of the claimed sponge in a taxonomically unacceptable form and inserting a comma before the word “wherein” at Line 1 of each of Claims 3, 7 and 24-25; paragraph;
- Indefiniteness rejection to Claim 25 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the phrase, “floral water”; and
- Obviousness rejection to Claims 1, 3, 7 and 24 under 35 U.S.C. § 103 (a) as obvious over combined teachings from RU 2 182 820 C1 in view of CN 1152455.

Claims Status

3. Claims 2, 4-6, 8-23 and 26 remain cancelled and Claim 27 has currently been cancelled.
4. Claims 1, 3, 7 and 24-25 have currently been amended.
5. Claims 1, 3, 7 and 24-25 are pending.

Objection to Abstract

6. The objection to the Abstract is withdrawn in view of applicants' amendment.

Claim Rejections – 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3 and 24 are rejected under 35 U.S.C. §102(b) as anticipated by Reka Farm (printed from http://www.reka-farm.ru/prod_e.htm 4/14/2008 4:53:43 PM).

Claims 1, 3 and 24 recite a pharmaceutical composition comprising approximately 50% to 60% insoluble material of substantially pure powder of *Spongilla lacustris* (i.e., *S. lacustris*)

and a pharmaceutically acceptable excipient. Said composition is applicable for treating skin diseases e.g., dermatitis and acne.

Regarding Claims 1, 3 and 24; Reka Farm publication teaches, “Badiaga was obtained, processed and applied even in the past century” (See, information printed in the right side Block on Page 1 of 3). Badiaga is a colonial freshwater sponge and colonies of coelenterate freshwater sponges –badiaga-*Spongilla lacustris* L, are harvested and dried during the summer season, packed and used as a medical remedy in a powdered form. Badiaga in form of “gruel-like mass” after mixing with boiling water is used as powder, ointment or cream for contusions and bruises (Lines 2-4 and Lines 6-8 under Figure of the main text page and Lines 7-10 on Page 1 of 2 Pages under “Some Advice”). Said reference further teaches that badiaga is applied to the skin and for acne (Page 1 of 2 Pages of “Some Advice”, Lines 23-26) and furthermore badiaga is applicable for treating hematomas, contrusions, post acne scars polishing wrinkles treating pustulres and removing skin dark spots (“FAQS” Page 1 of 2 Pages, Lines 8-16) . Thus, pharmaceutical preparations comprising substantially pure badiaga powder from *S. lacustris* in a pharmaceutically acceptable excipient (i.e., hot water) are well documented in the pharmaceutical/ cosmetics art for application in skin diseases and used for over a century for the skin applications. Furthermore, said composition must inherently comprise approximately 50% to 60% insoluble material of substantially pure powder of *Spongilla lacustris* as is recited in the claimed invention because the prior-art-recited powder of *Spongilla lacustris* is also in powder form and the pharmaceutical preparations comprise same pharmaceutical excipient (i.e., water) as is instantly claimed. Therefore, the prior art composition inherently must comprise same ingredients as instantly claimed and also function as claimed because the said prior art

composition is comprised of same components as the claimed composition (See e.g., In re Best, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections Under 35 U.S.C. § 103(a)

9. Claims 1, 3, 7 and 24 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Reka Farm (printed from http://www.reka-farm.ru/prod_e.htm 4/14/2008 4:53:43 PM) in view of Manconi et al ((2008. Global diversity of sponges (Porifera: Spongillina) in freshwater, Hydrobiologia, Volume 595 Page 27–33).

Claims 1, 3, 7 and 24 recite a pharmaceutical composition comprising a substantially pure powder of a freshwater sponge and a pharmaceutically acceptable excipient, wherein said freshwater sponge is *Spongilla lacustris*. The claimed pharmaceutical excipient is floral water. Said composition is applicable for treating skin diseases e.g., dermatitis and acne.

Regarding Claims 1, 3, 7, and 24 teachings from Reka Farm publication have been discussed at item 8, *supra*. Reka Farm Publication clearly describes that the sponge was available from Russian Federation lakes and rivers, but does not specifically identify the Astrakhan region. Manconi et al., teach, “*S. lacustris* is homeopathic remedy since 1700 with the common prelinnean Russian name of Badiaga” (See, Manconi et al., Page 32, Column 1, Line 1-11). Manconi et al. also teach, “an unusual practice known in cosmetics as in the case of young

ladies in Russia that, in 19th century, used dried spongillids to scrub their skin to have rosy cheeks, but some modern cosmetics are based on the same material”. Thus, pharmaceutical preparations comprising powdered *S. lacustris* along with a pharmaceutical excipient are well documented for at least a century to treat skin and skin diseases.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Reka Farm Publication in view of the teachings from Manconi et al. to obtain a composition comprising a substantially pure powder of a fresh water sponge and at least one pharmaceutically acceptable excipient, wherein said powder is a powder of *Spongilla lacustris* comprising approximately said freshwater sponge and floral water; because Reka Farm Publication teaches a composition comprising a dry powder of freshwater spongillidae , especially preparation of *S. lacustris* powder as cream or ointment for contrusions and bruises Manconi et al. teach application of preparations comprising *S. lacustris* as pharmaceutical and in medical applications.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify teachings from Reka Farms Publication with those of Manconi et al. to obtain a composition comprising a powder of freshwater sponge, especially *Spongilla lacustris* with at least one pharmaceutically acceptable excipient, wherein said excipient is floral water; because Reka Farms Publication teaches a pharmaceutical composition comprising dry powder of *Spongilla lacustris*. Manconi et al. teach *Spongilla lacustris* is applicable in pharmaceutical and medical. Absent evidence to the contrary, it would

be obvious to obtain the sponge from the rivers and lakes of the Astrakhan region as opposed to other lakes and rivers of the Russian Federation.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 1 and 24-25 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Reka Farm (printed from http://www.reka-farm.ru/prod_e.htm 4/14/2008 4:53:43 PM) in view of Manconi et al ((2008. Global diversity of sponges (Porifera: Spongillina) in freshwater, *Hydrobiologia*, Volume 595 Page 27–33) and further in view of Philippe et al (US Patent 7, 078, 047).

Claims 1 and 24-25 recite a pharmaceutical composition comprising a substantially pure powder of a freshwater sponge and a pharmaceutically acceptable excipient, wherein said freshwater sponge is *Spongilla lacustris*. The claimed pharmaceutical excipient is floral water. Said composition is applicable for treating skin diseases e.g., dermatitis and acne.

Regarding Claims 1 and 24-25 teachings from Reka Farm publication and Manconi have already been discussed at items 8-9 *supra*. Reka Farm Publication and MAnconi et al., however, do not teach the excipient water to be floral water. Phillippe et al. teach a pharmaceutical composition for skin treatment (See Abstract) and further teach mineral water or

floral water to be the excipient (Column 5, Line 11). Thus, pharmaceutical preparations comprising powdered *S. lacustris* along with a pharmaceutical excipient are well documented for at least a century to treat skin and skin diseases. Furthermore, floral water is a well established art-recognized pharmaceutical excipient.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Reka Farm Publication in view of the teachings from Manconi et al., and Philippe et al., to obtain a composition comprising a substantially pure powder of a fresh water sponge and at least one pharmaceutically acceptable excipient, wherein said powder is a powder of *Spongilla lacustris* as said freshwater sponge and floral water; because Reka Farm Publication teaches a composition comprising a dry powder of freshwater spongillidae , especially preparation of *S. lacustris* powder as cream or ointment for acne, bruises, contrusions and a number of skin diseases, Manconi et al. teach application of preparations comprising *S. lacustris* as pharmaceutical and in medical applications and Philippe et al. teach the floral water as an excipient in pharmaceutical preparations.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify teachings from Reka Farms Publication with those of Manconi et al., and Philippe et al., to obtain a composition comprising a powder of freshwater sponge, especially *Spongilla lacustris* with at least one pharmaceutically acceptable excipient, wherein said excipient is floral water; because Reka Farms Publication teaches a pharmaceutical composition comprising dry powder of *Spongilla lacustris*, Manconi et al. teach

Spongilla lacustris is applicable in pharmaceutical and medical applications and Philippe et al., teach floral water as a pharmaceutically acceptable excipient.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

11. For the aforementioned reasons, no claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

23 April 2008

/Jon P Weber/
Supervisory Patent Examiner, Art Unit 1657